REMARKS

This Amendment is responsive to the Office Action of October 30, 2002 and is being filed within four (4) months thereof. Claims 1-9 and 19-22 have been canceled without prejudice. Claims 10 and 23 have been amended. Claims 30-32 have been added. Therefore, Claims 10-18 and 23-32 are pending in this case.

A request for a two-month extension of time and the appropriate fees are enclosed. Please charge any additional fees or credit any overpayment to our Deposit Account No. 01-1960.

Reexamination and reconsideration are respectfully requested.

ELECTION

Applicant has canceled Claims 1-9 and 19-22 without prejudice.

CLAIM REJECTIONS - CLAIMS 10-18 & 23-29 - § 102

Claims 10-18 and 23-29 were rejected under 35 U.S.C. § 102(e) as being anticipated by Lee (US 2002/0001854 A1). Of the rejected claims, Claims 10 and 18 are independent.

Applicant's claimed apparatuses and methods are directed to testing for the presence of both drugs of abuse and adulterants in a bodily fluid with a single device. As discussed in the specification concerning the prior art, conventional approaches require separate devices and lead to several attendant drawbacks. By including an adulteration test strip and a drug test strip into a single apparatus, mix-ups are avoided as technicians would no longer need to pair an adulteration test result with the correct

drug test result. Furthermore, messy spills can also be minimized as droplets of the subject's bodily fluid can be deposited into the same device. At the same time, accuracy is preserved by keeping the adulteration test strip physically separate and detached from the drug test strip so as to prevent any fluid communication between the two.

Lee discloses an integrity determinant pad 300 that is attached to carrier membrane 303. The carrier membrane 303 serves to absorb the liquid and carry it to the various components attached thereto. One drawback with Lee, however, is that the test strip 105A is coupled to the same carrier membrane 303 that directs fluid to the integrity determinant pad 300.

Applicant has amended independent Claim 10 to recite that the drug test strip is detached from adulterant test strip. As shown in a preferred embodiment illustrated in Figure 1, the adulterant test strips 52 are detached from the drug test strips 26. Unlike Lee, Applicant's adulterant test strips and the drug test strips are not coupled to any common membrane. Fluid communication is completely prevented between the adulterant test strips and the drug test strips.

Applicant has also amended independent method Claim 23 to recite the step of disposing a drug test strip in a second region that is detached from the adulterant test strip. Lee's integrity determinant pad 300 is not detached from the drug test strip 105A because both strips are coupled to the same carrier membrane 303 that absorbs and directs the fluid.

Claims 10-18 were rejected under U.S.C. § 102(b) as being anticipated by Sun (US 5,962,336). The Office Action states that Sun discloses a multi-test panel with

several strips containing a separate and different immunochromatographic system. The Office Action admits that Sun does not disclose an adulterant test strip, but states that such a limitation is seen as an intended use of the device and is not given patentable weight.

Applicant has amended Claim 10 to include further structural limitations directed to the adulteration test strip. In particular, Claim 10 now recites a non-immunoassay adulterant test strip. As opposed to the immunoassay drug test strip which causes a liquid to wick up the strip, a non-immunoassay adulterant test strip will provide a color response simply upon contact with the liquid. Thus, the lateral flow action of immunoassays is absent in such adulterant strips. This is one of the reasons why adulterant strips need not be elongate (pg. 11, line 5). This distinction is further emphasized by one of Applicant's preferred embodiments shown in Figure 11. The purpose of the adulteration test strip 180 is to mimic the lateral flow of an immunoassay with an adulteration test pad 200 that was not an immunoassay.

To further clarify this feature and provide more structural limitations, Claim 10 has also been amended to recite that the adulterant test strip is configured to receive a sample of the bodily fluid and to display the adulteration test strips through the same aperture. Since lateral flow is not being performed with the adulteration test strips, the window through which drops of fluid are being deposited onto the adulteration test strip is the same window through which the results are displayed.

Such a feature is not shown in Sun and cannot be accomplished with Sun because Sun only discloses immunoassay strips which necessarily requires lateral flow. Therefore, as shown in Figure 1 of Sun, fluid is deposited in a first reception well 30

while results are displayed through a second window 28. Sun fails to disclose a non-immunoassay adulteration test strip, and further fails to disclose such a strip being configured to receive fluid and display test results through the same aperture.

Claims 10-18 and 23-29 were rejected under 35 U.S.C. 102(b) as being anticipated by Bogema (US 6,248,598). Bogema discloses a holder D that includes multiple test strips B. The Office Action acknowledges that Bogema does not disclose an adulteration strip.

Similar to Sun, Bogema fails to disclose a non-immunoassay adulteration test strip. Bogema describes its test strips as providing an "immunochomatographic assay of saliva by capillary flow." (col. 6:57-58). Bogema also fails to disclose an adulteration test strip that is configured to receive bodily fluid and display adulteration test results through the same aperture.

Applicant respectfully submits that independent Claims 10 and 23 are allowable over the cited references. Applicant further submits that dependent Claims 11-18 and 24-29 are allowable at least by virtue of their dependence from allowable Claims 10 and 23, for the further patentable features recited therein, and for any grounds as may be recognized by the Examiner.

ADDITIONAL CLAIMS – CLAIMS 30-32

Applicant has also proposed an additional set of apparatus claims including means-plus-function language. Independent Claim 30 recites, among other things, a means for detecting an adulterant in a first sample of a bodily fluid, and a means for

detecting a drug of abuse in a second sample of the bodily fluid. The drug testing means is detached from the adulterant detecting means.

Such means-plus-function limitations are not found in the cited prior art references.

Dependent Claim 31 recites that the adulterant detecting means comprises a non-immunoassay test strip. Dependent Claim 32 recites that the adulterant detecting means is configured to receive the first sample of the bodily fluid and to display detection results through the first aperture.

SUMMARY

Based on the above amendments and accompanying remarks, Applicant respectfully submits that all pending claims are in condition for allowance and requests a Notice of Allowance. Applicant encourages the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on March 26, 2003 by

Signature Angela Williams

March 26, 2003

Respectfully submitted,

Vic Lin
Registration No. 43,754
Myers Dawes Andras & Sherman
19900 MacArthur Boulevard, Suite 1150
Irvine, CA 92612
(949) 223-9600

Version With Markings To Show Changes Made

In the Claims:

The claims have been amended as follows:

Claims 1-9 have been canceled without prejudice.

10. (Amended) An apparatus for testing the presence of both drugs and adulterants in a bodily fluid, the apparatus comprising:

a first region;

a second region separate from the first region;

~~an~~ non-immunoassay adulterant test strip disposed in the first region;

a drug test strip disposed in the second region and detached from the adulterant test strip;

a first aperture disposed in the first region and open to the adulterant test strip, the adulterant test strip being configured to receive a sample of the bodily fluid and to display adulteration test results through the first aperture; and

a second aperture disposed in the second region and open to the drug test strip.

11. The apparatus of claim 10 wherein the first region comprises:

a first space for receiving the adulterant test strip; and

a first plurality of dividers preventing fluid communication between the drug test strip and the adulterant test strip.

12. The apparatus of claim 11 wherein the second region comprises:

a second space for receiving the drug test strip; and

a second plurality of dividers holding the drug test strip in place.

13. The apparatus of claim 10 further comprising a third aperture disposed in the second region, wherein:

the second aperture is open to an initial absorption portion of the drug test strip; and

the third aperture is open to an indicator portion of the drug test strip.

14. The apparatus of claim 10 further comprising a separator separating the first region from the second region.

15. The apparatus of claim 14 wherein the separator comprises a recessed floor in the first region.

16. The apparatus of claim 14 wherein the separator comprises a raised floor in the second region.

17. The apparatus of claim 14 wherein the separator comprises a barrier disposed between the first region and the second region.

18. The apparatus of claim 10 wherein the adulterant test strip comprises a backing, an absorption pad disposed on the backing, and an adulteration test pad disposed on the absorption pad.

Claims 19-22 have been canceled without prejudice.

23. (Amended) A method for manufacturing a combination drug and adulterant testing device, the method comprising:

providing a main body having at least a first region and a second region;

disposing an adulterant test strip in the first region;

disposing a drug test strip in the second region that is detached from the adulterant test strip;

separating the adulterant test strip from the drug test strip to prevent any fluid communication therebetween;

providing visual and physical access to the adulterant test strip with a first aperture in the first region; and

providing physical access to the drug test strip with a second aperture in the second region.

24. The method of claim 23 wherein providing a main body having at least a first region and a second region comprises providing a base and a cover.

25. The method of claim 24 wherein separating the adulterant test strip from the drug test strip to prevent any fluid communication therebetween comprises:

forming a first compartment for receiving the adulterant test strip; and

forming a separate second compartment for receiving the drug test strip.

26. The method of claim 25 wherein:

forming a first compartment for receiving the adulterant test strip comprises forming a recessed floor and a first plurality of protrusions surrounding the recessed floor; and

forming a second compartment for receiving the drug test strip comprises forming a recess and a second plurality of protrusions surrounding the recess.

27. The method of claim 26 wherein:

disposing an adulterant test strip in the first region comprises disposing the adulterant test strip in the first compartment; and

disposing a drug test strip in the second region comprises disposing the drug test strip in the second compartment.

28. The method of claim `24 wherein:

providing access to the adulterant test strip comprises forming a first aperture in the cover that is open to the adulterant test strip; and

providing access to the drug test strip comprises forming a second aperture in the cover that is open to the drug test strip.

29. The method of claim 28 further comprising forming a third aperture that is open to an indicator portion of the drug test strip.

The following claims have been added.

30. (Newly added) An apparatus for testing the presence of both a drug of abuse and an adulterant in a bodily fluid, the apparatus comprising:

a first region;

a second region separate from the first region;

means for detecting the adulterant in a first sample of the bodily fluid, the adulterant detecting means being disposed in the first region;

means for detecting the drug of abuse in a second sample of the bodily fluid, the drug detecting means being disposed in the second region and detached from the adulterant detecting means;

a first aperture disposed in the first region and open to the adulterant detecting means; and

a second aperture disposed in the second region and open to the drug detecting means.

31. (Newly added) The apparatus of Claim 30, wherein the adulterant detecting means comprises a non-immunoassay test strip.

32. (Newly added) The apparatus of Claim 30, wherein the adulterant detecting means is configured to receive the first sample of the bodily fluid and to display detection results through the first aperture.